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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/195,368	11/18/98	ASHKENAZI A	11669.26US03

EXAMINER	
SUN HOFFMAN, L	
ART UNIT	**PAPER NUMBER**
1642	10

DATE MAILED: 06/07/00

HM12/0607

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/195,368	Ashkenazl et al
Examiner	**Group Art Unit**
Lln Sun-Hoffman	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-9 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 10-26 are canceled.

Claims 1-9 are examined on the merits.

Claim Rejections - 35 USC § 112

2. Claim 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is improperly dependent from claim 1 because it did not further limit claim 1, because X in claim 1 only limits to positions 48 to 57.

Claim 1 should be recited as ---an isolated--- instead of "isolated" in line 1.

3. Claims 1, 3-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are drawn to an isolated nucleic acid comprising DNA encoding DNA 19355 polypeptide comprising amino acid residues X to 177 SEQ.ID NO: 1, wherein X is any one of amino acid residues 48 to 57 of SEQ ID NO:1.

The claims are further drawn to vectors comprising the above sequences and host cells transfected with them.

The specification discloses an isolated cDNA sequence, SEQ ID NO: 2, which encodes a predictive polypeptide sequence, SEQ ID NO. 1. Absent evidence to the contrary, each of the sequence that encoding for an amino acid from residues of (48, 49 . . . or 57) to 177 is deemed to be an incomplete cDNA. Because the cDNAs are not full-length, a sequence prepared from undefined parts of a cDNA clone will not comprise the entire coding region of any particular gene, nor is it clear the partial sequence is even in a frame to encode a polypeptide. The claims, as written, however, encompass polynucleotides which vary substantially in length and also in nucleotide composition. The broadly claimed genus additionally, encompasses alternative spliced variants, as well as genes incorporating only portions of the disclosed sequence.

The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions which are

critical to the structure and function of the genus claimed. The specification proposes to discover other members of the genus. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed and no identifying characteristic or property of the instant polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific nucleotide sequences and the ability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

4. Claims 1, 3-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a SEQ ID NO: 1, does not reasonably provide enablement for any fragment comprising amino acid residues from positions 48, 49, 50 . . . or 57 to 177. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those In the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification teaches a SEQ ID NO: 1 which can activate NF-kB. However, the specification fails to teach whether a fragment from position of 48-177 and thereof also possess the same function. The DNA and protein arts are recognized as unpredictable, such that minor changes in the nucleotide or amino acid sequences of these molecules may produce profound changes in biological activity (CITE). A classic example of this is sickle cell anemia arising from a single amino acid substitution of valine for glutamic acid as the sixth amino acid in the beta chain of hemoglobin A. Genomic sequences display some elements of conservation of sequence among individuals and taxonomic species. However, genetic and protein sequences are characterized by a marked degree of variation or polymorphism. In almost all cases one is not able to predict the functional significance of particular sequence polymorphism. The art has not yet been able to decipher predictable and workable relationships between DNA/protein sequence polymorphism and functional activity. Many factors contribute to the unpredictability of this art. For example, it is important, when evaluating the potential effect of mismatches, to know if they are randomly distributed through the protein, clustered in one or more domains, or if mismatches are

located/concentrated in known critical areas of the molecule. In this art, establishing the function of a gene sequence still requires expression of the gene, and empirical characterization of the protein product. Further, many genes share sequence homology relationship within large and markedly heterogenous families, encompassing proteins that may share certain structural domains, but are associated with a variety of different biological functions. Determining specific function in such diverse families requires distinguishing the particular structure/function relationship of the claimed family member from the array of different function exhibited by divergent members of the family.

Claim Rejections - 35 USC § 102 251

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1, 3-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Yu et al.. (US Patent Number 5998171, priority date Aug. 16, 1996).

Yu et al teach a sequence (SEQ ID NO:2) which is identical to the fragment from positions 48, 49, 50 or 57 to 177, of SEQ ID NO:1.

Yu et al further teach a vector (column 12, lines 48-61) and host cells such as CHO, E.coli or yeast (column 13, lines 23-29). Therefore, the reference anticipates the claims.

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lin Sun-Hoffman, Ph.D., whose telephone number is (703)-308-7552. The examiner can normally be reached on Monday to Friday from 7:30 am to 4:00 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, Ph.D., who can be reached on (703) -305-3995.

Lin Sun-Hoffman, Ph.D.

YVONNE EYLER, PH.D
PRIMARY EXAMINER

June 5, 2000